

## CLAIMS

What is claimed is:

- 5           1.       A composition for delivering an agent to a target cell, comprising:
  - (a)     a microorganism that has, on its cell surface, at least one exogenous molecule that binds to an antigen on the surface of a target cell; and
  - (b)     an agent.
- 10          2.       The composition of claim 1, wherein the microorganism is selected from the group consisting of algae, bacteria, fungi, and protozoa.
3.       The composition of claim 2, wherein the microorganism is a bacterium.
- 15          4.       The composition of claim 3, wherein the bacterium is selected from the group consisting of *Escherichia coli*, *Mycobacterium*, *Salmonella*, and *Shigella*.
5.       The composition of claim 4, wherein the *Salmonella* is *Salmonella typhimurium* VNP20009 or *Salmonella typhimurium* SL7207.
- 20          6.       The composition of claim 1, wherein the microorganism expresses the exogenous molecule.
7.       The composition of claim 6, wherein the microorganism transiently expresses
- 25     the exogenous molecule.
8.       The composition of claim 1, wherein the microorganism is attenuated.
9.       The composition of claim 1, wherein the exogenous molecule is a polypeptide
- 30     or a fragment thereof.
10.      The composition of claim 9, wherein the polypeptide is an antibody.

11. The composition of claim 10, wherein the antibody is a mammalian antibody.

12. The composition of claim 11, wherein the antibody is a human antibody.

13. The composition of claim 10, wherein the antibody is a chimeric antibody.

5

14. The composition of claim 13, wherein the chimeric antibody is a humanized antibody.

15. The composition of claim 10, wherein the antibody is a single-chain antibody.

10

16. The composition of claim 1, wherein the target cell is a neoplastic cell.

17. The composition of claim 16, wherein the neoplastic cell is a solid-tumor cell.

15

18. The composition of claim 17, wherein the solid-tumor cell is a colon-tumor cell.

19. The composition of claim 16, wherein the neoplastic cell is a carcinoembryonic-antigen- (CEA)-expressing cell.

20

20. The composition of claim 19, wherein the CEA-expressing cell is selected from the group consisting of a bowel cancer cell, a breast cancer cell, a cervical cancer cell, a colon cancer cell, an esophageal cancer cell, a head cancer cell, a liver cancer cell, a lung cancer cell, a neck cancer cell, an ovarian cancer cell, a pancreatic cancer cell, and a stomach cancer cell.

25

21. The composition of claim 20, wherein the CEA-expressing cell is a colon cancer cell.

30

22. The composition of claim 16, wherein the antigen is a neoplasm-specific antigen.

23. The composition of claim 16, wherein the antigen is selected from the group consisting of CAK1, CDK4, CDR2, carcinoembryonic antigen (CEA), disialoganglioside GD2, HER-2, large external antigen (LEA), MAGEs, MUC1, p21, podocalyxin, Ras, UK114, and WT1.

5

24. The composition of claim 23, wherein the antigen is a CEA.

25. The composition of claim 1, wherein the agent is selected from the group consisting of a diagnostic agent, a labelling agent, a preventive agent, and a therapeutic agent.

10

26. The composition of claim 25, wherein the therapeutic agent is selected from the group consisting of an anti-tumor compound, a lipid, a nucleic acid, a polypeptide, a polysaccharide, and a pro-drug.

15

27. The composition of claim 26, wherein the nucleic acid is a plasmid.

28. The composition of claim 27, wherein the plasmid comprises at least one gene-silencing cassette.

20

29. The composition of claim 27, wherein the plasmid is an expression plasmid.

30. The composition of claim 25, wherein the polypeptide is selected from the group consisting of an antibody, an anti-proliferation factor, an immuno-enhancing factor, a pro-apoptotic factor, a pro-drug converting enzyme, and any fragment thereof.

25

31. The composition of claim 30, wherein the polypeptide is modified by glycosylation or lipid linkage.

32. A vaccine comprising:

30

(a) at least one microorganism that has, on its cell surface, at least one exogenous molecule that binds to an antigen on the surface of a target cell;

(b) an agent; and

- (c) a pharmaceutically-acceptable carrier.

33. A method for treating neoplasia in a subject in need of treatment, comprising administering to the subject a therapeutic composition in an amount effective to treat the neoplasia, wherein the therapeutic composition comprises:

- (a) a microorganism that has, on its cell surface, at least one exogenous molecule that binds to an antigen on the surface of a neoplastic cell in the subject; and  
(b) a therapeutic agent.

10 34. The method of claim 33, wherein the neoplasia is a solid tumor.

35. The method of claim 34, wherein the solid tumor is a colon tumor.

15 36. The method of claim 35, wherein the solid tumor expresses carcinoembryonic antigen (CEA).

37. The method of claim 36, wherein the solid tumor is selected from the group consisting of a bowel tumor, a breast tumor, a cervical tumor, a colon tumor, an esophageal tumor, a head tumor, a liver tumor, a lung tumor, a neck tumor, an ovarian tumor, a pancreatic tumor, and a stomach tumor.

38. The method of claim 37, wherein the solid tumor is a colon tumor.

25 39. The method of claim 33, wherein the microorganism is selected from the group consisting of algae, bacteria, fungi, and protozoa.

40. The method of claim 39, wherein the microorganism is a bacterium.

30 41. The method of claim 40, wherein the bacterium is selected from the group consisting of *Escherichia coli*, *Mycobacterium*, *Salmonella*, and *Shigella*.

42. The method of claim 41, wherein the *Salmonella* is *Salmonella typhimurium* VNP20009 or *Salmonella typhimurium* SL7207.

43. The method of claim 33, wherein the microorganism expresses the exogenous  
5 molecule.

44. The method of claim 43, wherein the microorganism transiently expresses the exogenous molecule.

45. The method of claim 33, wherein the microorganism is attenuated.  
10

46. The method of claim 33, wherein the exogenous molecule is a polypeptide or a fragment thereof.

47. The method of claim 46, wherein the polypeptide is an antibody.  
15

48. The method of claim 47, wherein the antibody is a mammalian antibody.

49. The method of claim 48, wherein the antibody is a human antibody.

50. The method of claim 47, wherein the antibody is a chimeric antibody.  
20

51. The method of claim 50, wherein the chimeric antibody is a humanized antibody.

52. The method of claim 47, wherein the antibody is a single-chain antibody.  
25

53. The method of claim 33, wherein the antigen is a neoplasm-specific antigen.

54. The method of claim 33, wherein the antigen is selected from the group  
30 consisting of CAK1, CDK4, CDR2, carcinoembryonic antigen (CEA), disialoganglioside GD2, HER-2, large external antigen (LEA), MAGEs, MUC1, p21, podocalyxin, Ras, UK114, and WT1.

55. The method of claim 54, wherein the antigen is a CEA.

56. The method of claim 33, wherein the therapeutic agent is selected from the  
5 group consisting of an anti-tumor compound, a lipid, a nucleic acid, a polypeptide, a polysaccharide, and a pro-drug.

57. The method of claim 56, wherein the nucleic acid is a plasmid.

10 58. The method of claim 57, wherein the plasmid comprises at least one gene-silencing cassette.

59. The method of claim 57, wherein the plasmid is an expression plasmid.

15 60. The method of claim 59, wherein the expression plasmid is transferred into the neoplastic cell.

61. The method of claim 59, wherein the expression plasmid expresses at least one peptide in the neoplastic cell.

20

62. The method of claim 56, wherein the polypeptide is selected from the group consisting of an antibody, an anti-proliferation factor, an immuno-enhancing factor, a pro-apoptotic factor, a pro-drug converting enzyme, and any fragment thereof.

25 63. The method of claim 62, wherein the polypeptide is modified by glycosylation or lipid linkage.

64. The method of claim 56, wherein the peptide is secreted into the neoplastic cell.

30

65. A method for treating neoplasia in a subject in need of treatment, comprising administering to the subject a therapeutic composition in an amount effective to treat the neoplasia, wherein the therapeutic composition consists of a microorganism that has, on its cell surface, at least one exogenous molecule that binds to an antigen on the surface of a
- 5 neoplastic cell in the subject.